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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,275	02/05/2002	Edward J. Petrus	EJP-2002-2	3053
7590 07/27/2004		EXAMINER		
EDWARD J. PETRUS 3413 SPANISH OAK DR.			LEWIS, PATRICK T	
AUSTIN, TX			ART UNIT	PAPER NUMBER
			1623	
	•		DATE MAILED: 07/27/2004	•

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)					
Office Action Summary		10/068,275		PETRUS, EDWARD J.				
		Examiner	Art Unit					
		Patrick T. Lewis	1623					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
THE I - Exter after - If the - If NO - Failu Any	ORTENED STATUTORY PERIOD FOR REP MAILING DATE OF THIS COMMUNICATION nsions of time may be available under the provisions of 37 CFR 1 SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reperiod for reply is specified above, the maximum statutory perion reto reply within the set or extended period for reply will, by staturely received by the Office later than three months after the mailed patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, howeve ply within the statutory minim d will apply and will expire SIX te, cause the application to by	r, may a reply be timely filed um of thirty (30) days will be considered time (6) MONTHS from the mailing date of this of the come ABANDONED (35 U.S.C. § 133).	ely. communication.				
Status								
1)□	1) Responsive to communication(s) filed on							
2a) <u></u>	☐ This action is FINAL . 2b) ☐ This action is non-final.							
3)								
	closed in accordance with the practice under	Ex parte Quayle, 19	35 C.D. 11, 453 O.G. 213.					
Disposition of Claims								
4)🖂	☑ Claim(s) <u>1-13</u> is/are pending in the application.							
	4a) Of the above claim(s) is/are withdrawn from consideration.							
5)	Claim(s) is/are allowed.							
-	6)⊠ Claim(s) <u>1-13</u> is/are rejected.							
	Claim(s) is/are objected to.							
8)[_	Claim(s) are subject to restriction and	or election requireme	ent.					
Applicati	on Papers							
9)[The specification is objected to by the Examir	ner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.								
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority u	ınder 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received.								
2. Certified copies of the priority documents have been received in Application No								
3. Copies of the certified copies of the priority documents have been received in this National Stage								
	application from the International Bure			J				
* See the attached detailed Office action for a list of the certified copies not received.								
Attachmen								
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)		erview Summary (PTO-413) per No(s)/Mail Date					
3) Inform	nation Disclosure Statement(s) (PTO-1449 or PTO/SB/0	3) 5) 🔲 No	tice of Informal Patent Application (PT	nformal Patent Application (PTO-152)				
Pape	Paper No(s)/Mail Date 6) Uther:							

Application/Control Number: 10/068,275

Art Unit: 1623

DETAILED ACTION

Information Disclosure Statement

1. The disclosure does not contain references listed on a proper information disclosure statement. Therefore, unless the references have been cited by the examiner on form PTO-892, applicant should not assume references have been considered.

Double Patenting

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

- 3. Claims 1-7 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7 of prior U.S. Patent No. 6,346,519. This is a double patenting rejection.
- 4. Claims 8, 10, 11, and 13 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3, 4, and 6 of prior U.S. Patent No. 6,656,925. This is a double patenting rejection.

Application/Control Number: 10/068,275

Art Unit: 1623

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-7, 9, and 12 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,656,925. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1-7 are drawn to a method for treating arthritis in mammals by administering a therapeutically effective amount of a composition comprising an inhibitor or nitric acid synthase and an aminosugar. Claim 2 limits the aminosugar in the composition. Claim 3 requires an additional agent. Claim 4 further requires that the composition has an enteric coating. Claim 5 further requires that the composition comprises a carrier. Claims 6-7 further limit the inhibitors of nitric oxide synthase. Claims 9 and 12 are drawn to a composition comprising an inhibitor of nitric oxide production and an amino sugar. Claim 9 further limits the inhibitors of nitric oxide production. Claim 12 reads upon a composition that optionally uses a controlled

Application/Control Number: 10/068,275

Art Unit: 1623

release method of enteric coating to deliver the composition orally into the gastrointestinal tract.

The instantly claimed method for treating arthritis in mammals differs from the method claimed in the '925 patent in that composition of the '925 patent employs an inhibitor of nitric oxide production compared to an inhibitor of nitric oxide synthase; however, there is substantial overlap in the inhibitors employed (both methods employ zinc compounds, arginine derivatives, redox dyes, L-canavarine, and methylene blue for example). Applicant should also note that there may be possible typographical errors in claims 2, 5, and 8 of the '925 patent. For example, claims 2 and 5 are drawn to "the method of claim 1"; however, claim 1 is drawn to a composition. A proper dependent claim incorporates all of the limitations of the independent claim. The examiner has been interpreted claims 2 and 5 to read upon "the composition of claim 1". Claim 8 has been interpreted to read upon "the method of claim 7".

Conclusion

7. Claims 1-13 are pending. Claims 1-13 are rejected. No claims are allowed.

Art Unit: 1623

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on M-F 10:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

atrick T. Lewis, PhD

Examiner Art Unit 1623